

TCT-291**Coronary artery bifurcation stenting using a dedicated side branch stent combined with DES (Facilitated Culottes) : Two years clinical outcome**

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Background: Treatment of coronary bifurcation lesions with stenting has been associated with increased complication rate and remains a major challenge in intervention cardiology. Introduction of DES reduced restenosis in the main branch. However, restenosis at the ostium of the side branch remains a problem. As part of an international registry we evaluated the clinical safety and efficacy of Tryton a dedicated side branch stent. In this study we sought to determine the clinical outcome of facilitated culottes in coronary artery bifurcation stenting using Tryton stent.

Methods: We prospectively looked at 169 consecutive patients who had bifurcation lesion and treated with Tryton stent.

Results: Males constitute 80.5% with mean age of 68 and 33.7% were age above 70 years. The target lesion was LAD/Diagonal bifurcation in 54.5%, LCX/OM in 30.3% and RCA bifurcation in 14.1%. All were de novo lesions and cases of CTO, graft lesions and ISR were not included. Stent was successfully implanted in 99.4% and there was one case of proximal migration of stent after fully deployed. Dissection at distal edge of Tryton occurred in 8 cases and treated with DES. Clinical follow up was completed in all patients and all stayed on aspirin and clopidogrel. Over a period of 12-24 months follow up, there was no cardiac death, emergency CABG or acute/sub-acute stent thrombosis. Over all incidence of major adverse cardiac event (MACE) was 10.1% and target vessel revascularisation was encountered in 5.6%. There were 18 admissions for non-related medical conditions and 12 cases for elective PCI to a different coronary artery.

Conclusion: Facilitated Culottes stenting using the Tryton stent combined with a 'workhorse DES' is feasible and safe in a broad spectrum of 'unselected bifurcation lesions'. This technique, completed with systematic 'four step kissing' balloon dilatation is associated with favourable clinical outcomes, with low rate of MACE and TLR, comparable with our prior experience with 'conventional culottes' stenting using DES.

TCT-292**Use of a Dedicated Sidebranch Device for Bifurcation Disease: A Single Centre Experience of the TRYTON Stent**

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Background: The optimal strategy for bifurcations has yet to be defined. Data suggest that "provisional" side-branch (SB) stenting is superior to complex 2-stent approaches, but the role of customised devices such as the TRYTON SB stent has not been examined. This is a non-drug eluting, Cobalt Chromium stent which is deployed into the SB. A second stent is mandated in the main branch (MB), deployed through TRYTON in a culottes fashion to cover the carina and secure TRYTON in place. Final kissing balloon inflation is required.

Methods: Since November 2008, 71 patients (mean age 63 yrs, range 36-84) with Medina classified bifurcations and SB diameters of at least 2.5 mm were selected for treatment with TRYTON. Lesions were in the left anterior descending/diagonal (51), circumflex/marginal (11), right coronary artery (5) and left main stem (4).

Results: Procedural success was 93%. In 5 cases from our initial 6 months' experience, TRYTON could not be delivered because of calcification or tortuosity requiring retrieval in 1, and resulting in dislodgement in 4. All 5 were treated with an alternative strategy and none had clinical sequelae. Subsequent device modification improved balloon adherence, trackability and deliverability. In 66 patients TRYTON was deployed successfully and in all but one a drug eluting stent (DES) was used in the MB. Additional DES were deployed into other diseased segments of the SB in 7 and the MB in 11. Final kissing balloon inflation was performed in all but one case (98%). Angiographic success in both MB and SB was 100%. After 15 months (mean, range 1-31) there have been no myocardial infarctions or deaths. Three patients were reinvestigated because of recurrent symptoms, only one requiring further treatment with a drug eluting balloon because of diffuse in-stent restenosis in a bare metal MB stent.

Conclusion: TRYTON performs predictably and successfully scaffolds the SB ostium. Our medium term results are encouraging and in accord with registry data. A randomised trial comparing TRYTON with provisional side-branch stenting is ongoing.

TCT-293**Advanced Bifurcation Systems Mother-Daughter Platform in Complex Coronary Bifurcations: Prospective, Multicenter First-in-Man Experience**

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Background: The ABS platform for provisional and full bifurcation stenting is designed for automatic orientation and alignment of main branch and side branch stents

with complete coverage in a simple procedure.

Methods: The ABS platform is a dual-catheter, independently movable system. The full stenting system (MD-BI) consists of a Mother-Daughter Stent (MDS) and a Daughter Stent (DS). The MDS has an aperture through which the daughter balloon catheter (DC) protrudes and leads the system. The MDS is circumferentially crimped on it's delivery balloon distal to this aperture. It is only partially crimped proximal to the aperture so that the shaft of the DS catheter slides freely. The DS delivery balloon is equal in length to the proximal segment of the MDS, and DS combined. The DS is mounted on the distal half of this balloon. The system is loaded on main and side branch wires and advanced to the carina. The DS which now is in the daughter vessel is pulled back while the MDS is held in place. Pull back is completed when the proximal half of the DC balloon is in the proximal segment of the MDS and the two proximal balloon markers are aligned. The DC balloon is inflated, deploying the proximal segment of the MDS, as well as the DS, ensuring contiguous alignment of the two stents and proper orientation of the proximal segment of the MDS. This automatic alignment is against the only fixed structure in any bifurcation namely the carina. Patients with de novo lesions were enrolled in this pilot, non-randomized, multicenter trial evaluating the safety, feasibility, and acute efficacy.

Results: Results are available for 10 patients to date (all median 1, 1, 1). The device was deployed in the following sites: LAD- Diag, LCx-OM, and PDA-PLB. The provisional system (MD-P) has been deployed in 3 patients so far. Procedural success was 100% with complete tissue coverage. The 30 and 180-day composite MACE and TVR were 0. All patients are free of angina. Angiographic follow-up to date has been completed in 5 patients and has revealed edge re-stenosis in 2 side-branch vessels only. The carina has remained widely patent with no evidence of re-stenosis.

Conclusion: The ABS platform permits stenting of bifurcation lesions regardless of branch angulation in a short and simple procedure. This pilot first-in-human study provides evidence of feasibility and short-term efficacy.

TCT-294**Acute Procedural Outcome in Patients Treated With a Dedicated Bifurcation Stent for Left Main Stem Disease - The TRYTON LM Multicentre Registry**

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Background: Left main stem (LM) bifurcation stenting is associated with suboptimal outcome with the use of conventional stents. The use of a dedicated bifurcation stent-the TRYTON sidebranch stent in conjunction with a conventional stent may facilitate stenting and potentially improve angiographic results and outcome in LM bifurcation stenting.

Methods: Patients with LM stenting with the TRYTON sidebranch stent were enrolled in a dynamic prospective multicentre registry. Clinical procedural and follow-up data as well as angiography films were collected and analysis including quantitative angiography was performed in a core lab.

Results: 23 patients [age 68±8 yrs; 18 (78%) male; 3 (13%) unstable angina] were included. Medina class was 1,1,1 in 13 (57%); 1,0,1 in 4 (17%); 1,1,0 in 3 (13%) and 1,0,0 in 3 (13%). Predilatation of the main vessel (MV) was performed in 16 (74%), of the sidebranch (SB) in 20 (87%) while kissing predilatation was performed in 4 (17%). The Tryton stent on a stepped balloon with diameter 3.5-2.5mm was used in 19 (85%), diam. 3.5-3.0 in 2 (9%) and that on a straight balloon in 1 (4%). Delivery failure occurred in 1 patient. The MV stent diameter was 3.5±0.5mm with an everolimus eluting stent employed in 19 (86%) of cases. An additional stent in the side-branch was required in 9 (41%) cases, 2 (9%) of which for dissection. Final kissing balloon was performed in all patients. Acute gain was 1.22±0.84 in proximal MV, 0.94±0.80 in distal MV and 0.61±0.58 in SB. Angiographic success was achieved in 100%. Technical success reached 96 %. Procedural success in 91% (2 PCI-related myocardial infarction). At 30 days, no further events were reported. Thus MI rate was 9% (2- both procedural), stent thrombosis 0%, TVR/TLR 0% and cardiac death 0%.

Conclusion: The use of the TRYTON sidebranch stent for treatment of LM bifurcation disease is feasible and results in an optimal angiographic appearance. The safety of the procedure and 30 day outcome is acceptable. Further safety and efficacy studies with long term outcome of this strategy are warranted.

TCT-295**Crush Versus Culotte for the Treatment of Coronary Bifurcations: Insights From a Long-term Follow-up**

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Background: The crush (CS) and culotte (CT) techniques have shown similar short-term outcomes for the treatment of bifurcation lesions. Nonetheless, no data on long-term follow-up comparing the two strategies has been published to date. The objective of the present study was to evaluate the long-term outcomes of patients who underwent percutaneous coronary intervention (PCI) using a CS or CT technique for a bifurcated lesion.

Methods: We used a prospective bifurcation registry at a large Canadian teaching